

(STP-06-021, March, Program, SA-300)

March 8, 2006

|

|

C. Nuclear Material Event Database (NMED)

NMED contains an historical collection of information on the occurrence, description, and resolution of events involving the use of radioactive material in the United States (source, byproduct, special nuclear material, and in some cases, naturally occurring, and accelerator-produced radioactive material). NMED accommodates the sharing of material event data submitted by Agreement States, non-Agreement States, and NRC licensees. NMED is maintained by the NRC's Office of Nuclear Material Safety and Safeguards (NMSS). The NMSS contractor, Idaho National Laboratory (INL), is responsible for coding and quality control of information.

IV. ROLES AND RESPONSIBILITIES

- A. The Director, Office of State and Tribal Programs (STP), is responsible for the collection, coordination and, in cooperation with NMSS and the Office of Nuclear Regulatory Research (RES), the review of reports of incidents and events that have occurred involving the use of nuclear materials received ge terelice by Office ofSe[(h anhncllorts ofegul), it DatSIRse (NM that

SA-300 <i>Reporting Material Events</i>	
--	--

- b. Inform the Event Project Manager or the Project Manager's backup, the STP Director and Deputy Director. STP staff should inform the RSAO.

2. E-mail, FAX, or Written (Hard Copy) Event Reports

- a. A copy of the event report should be provided to the Director and Deputy Director, STP, and the appropriate ASPO. A copy should also be sent to the NMED contractor, INL, through the STP Director's Secretary.
- b. Agreement State event report to be reviewed by the Events

--	--

NRC [Management Directive 8.5](#), *Operational Safety Data Rewew*, December 23, 1997.

STP Procedure [SA-100](#), *Implementation of the Integrated Materials Performance Evaluation Program (IMPEP)*.

STP Procedure [SA-105](#), *Rewewing Common Performance Indicator #5, Response to Incidents and Allegations*.

STP Procedure [SA-117](#), *Agreement State Project Officers (ASPOs)*.



Abstract

The review and analysis of operational event information increases the effectiveness of the U.S. Nuclear Regulatory Commission (NRC) and Agreement State regulatory programs by identifying safety and security significant events and concerns, and their causes. The information from reports of medical events, overexposures, equipment failures, and other events that have occurred involving the use of nuclear materials licensed by either NRC or the Agreement States is invaluable in assessing trends or patterns and identifying possible inadequacies or unreliability of specific equipment or procedures. The reported information will significantly aid in understanding why the events occurred and identifying any actions necessary to improve the effectiveness of NRC and Agreement States regulatory programs. The information is also used in preparation of NRC's performance report to Congress.

This handbook, which supercedes the previous May 23, 2001 version, has been developed to provide information to the staff of the Agreement and non-Agreement States that are responsible for the preparation of event reports for incidents and events involving the use of nuclear materials that have occurred in their State. Reporting of Agreement State material events to

followed in procedure toance report to Co

Table of Contents

	Page
<i>Abstract</i>	iii
1. Introduction	1
1.1 Why do we collect event information?	1
1.2 What is the governing regulatory authority?	2
1.3 How do you determine if an event is reportable?	3
1.4 What is the Nuclear Materials Events Database?	3
1.5 Reporting Lost, Stolen and Abandoned Sources	4
1.6 Reporting Theft or Terrorist Activity Events	5
2. Reporting Material Events	7
2.1 Reporting Significant Events (Reportable within 24 hours by Agreement State licensee)	7
2.2 Initial NMED Record for Significant Events	7
2.3 Radiological Emergency Response Assistance Available to the States for Significant Material Events	8
2.4 30 - 60 Day Event Notification	10
2.5 Reporting Follow-up Event Information	11
3. Closing and Completing NMED Records	14
3.1 Events Closed in NMED	15
3.2 Record Complete in NMED	15

1. Introduction

This handbook contains guidance for Agreement States on reporting material event information to the Nuclear Regulatory Commission (NRC) for events that have occurred in their State. It also provides guidance for use by non-Agreement States when reporting



¹ Nuclear Regulation: Better Criteria and Data Would Help Ensure Safety of Nuclear Materials, GAO/RCED-93-90.

|

|

--	--



Reportable within 24 hours under 10 CFR 20.2203 20.2203, 30.50(a)	Exposure to Nonradiation Worker at a Licensed Facility



describes sources that could be used for malicious purposes to cause harmful effects.
“Immediately” is interpreted as 4 hours after an Agreement State has been notified of the

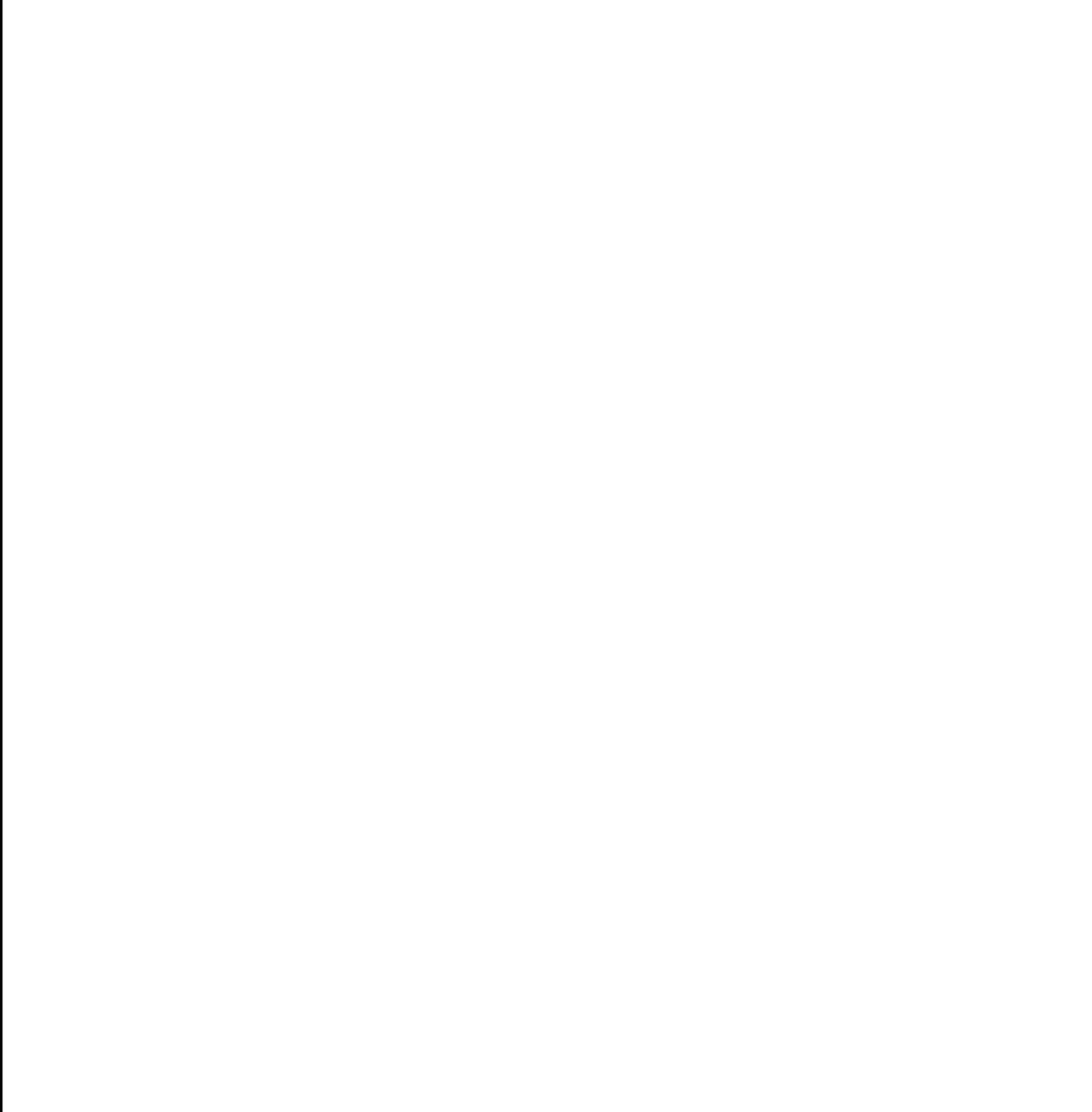
Table 3: Radionuclides of Concern

Radionuclide	Quantity of Concern ¹ (TBq)	Quantity of Concern ² (Ci)
Am-241	0.6	16
Am-241/Be	0.6	16
Cf-252	0.2	5.4
Cm-244	0.5	14

2. Reporting Material Events



|



--	--	--

d. ***Internet Access to NMED***

An NMED search of the nationally collected data is available on the website with several drop-down point-and-click menus available. Users may download the latest NMED national database information via Internet file transfer. Internet access to the NMED is controlled through INL. If access is required, contact the INL NMED Project Manager by email message at: NMED@inl.gov or the NRC NMED Project Manager by email message at: NMEDNRC@nrc.gov. *NOTE: Agreement States should continue to use the Microsoft Access data entry program for maintaining a local events database and for submitting*



EXHIBIT 2 - SAMPLE EVENT REPORT COVER PAGE

AGREEMENT STATE

EVENT REPORT ID NO. ____ - ____ - ____
(State\YY\No.)

DATE:

TO:

Director
Office of State and Tribal Programs

SUBJECT:

STATE:

Signature and Title: _____

<p>Public Availability of Event Information: Any event information that is considered preliminary predecisional information by the State should be clearly identified on the cover page as follows: "Preliminary, Not for Public Disclosure." For event information in NRC's possession, the final determination on whether to withhold from public disclosure will be made by NRC on a case-by-case basis in accordance with the requirements of 10 CFR Part 9.</p>
--

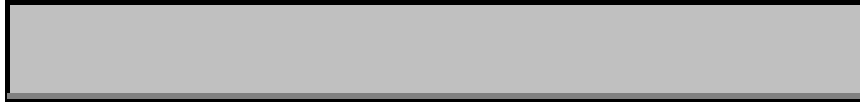


|

|

4. N

4.1 *Event Notifications (ENs) are Available on Internet*



5. NRC Safety Reviews of Material Event Reports

5.1 NRC Review of Material Events for Safety Significance and Generic Assessment

A weekly review all of new material event notifications (ENs) received by the Headquarters Operations Center and event notifications and follow-up reports,

If necessary, NRC staff may contact Agreement States for additional information on ~~significant events~~ ~~significant events~~ pose health and safety or security risks.

Such requests, normally initiated by the RSAO, would occur on an as needed basis, possibly within hours to a few days of notification of the occurrence of the event, based on the safety significance.



- (1) Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission;
- (2) Major degradation of essential safety-related equipment;
or
- (3) Major deficiencies in design, construction, use of, or management controls for facilities or radioactive material licensed by or otherwise regulated by the Commission.

The annual AO Reports to Congress are accessible at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/>.

The AO Report to Congress is also used as used to provide information on significant material issues and on adverse licensee performance. In accordance with SECY-02-216, "Proposed Process for Providing Information on Significant Nuclear Material Issues and Adverse License Performance," Agreement State events will be considered, along with other material licensees, for discussion during the Annual Agency Action Review Meeting (AARM). The review



³ An “unintended radiation exposure” in

⁵ The wrong radiopharmaceutical as used in the AO criterion for medical events refers to any radiopharmaceutical other than the one listed in the written directive or in the clinical procedures manual.

6.4 Guidelines for AO Write-ups

All AO write-ups should be complete, up-to-date, and written using text that is





~~Health Effect on oncologists
patient effect to the patient, and
Consultant Tennessee consu
Where applicable, the term affects~~

administration may be a
injury and may produce
long-term follow-up

as a result of the eligible for failure to

Epidemiology and Heal
study. The licensee cor
identify and respond to
resulting from this adm
follow-ups on the patien

Cause or causes

Appendix

Glossary

ADAMS Agencywide Documents Access and Management System, NRC's official

References

The following is a list of NRC documents, manuals and procedures that contain additional information on event response and AOs.

NRC Policy

June 30, 1997 Staff Requirements Memorandum, Procedures for *Statement of Principles and Policy for the Agreement State Program and Policy Statement on Adequacy and Compatibility of Agreement State Programs*.

NRC Report

Performance Budget FY2006, NUREG-1100, Vol. 21, February 2005, annual report to Congress required by GPRA.

NMSS Licensee Newsletter, NUREG/BR-0017 ***NRC Management Directives***

- 6.4 Generic Issues Program
- 8.1 Abnormal Occurrence Reporting Procedures
- 8.10 NRC Medical Event Assessment Program

NRC Inspection Manual

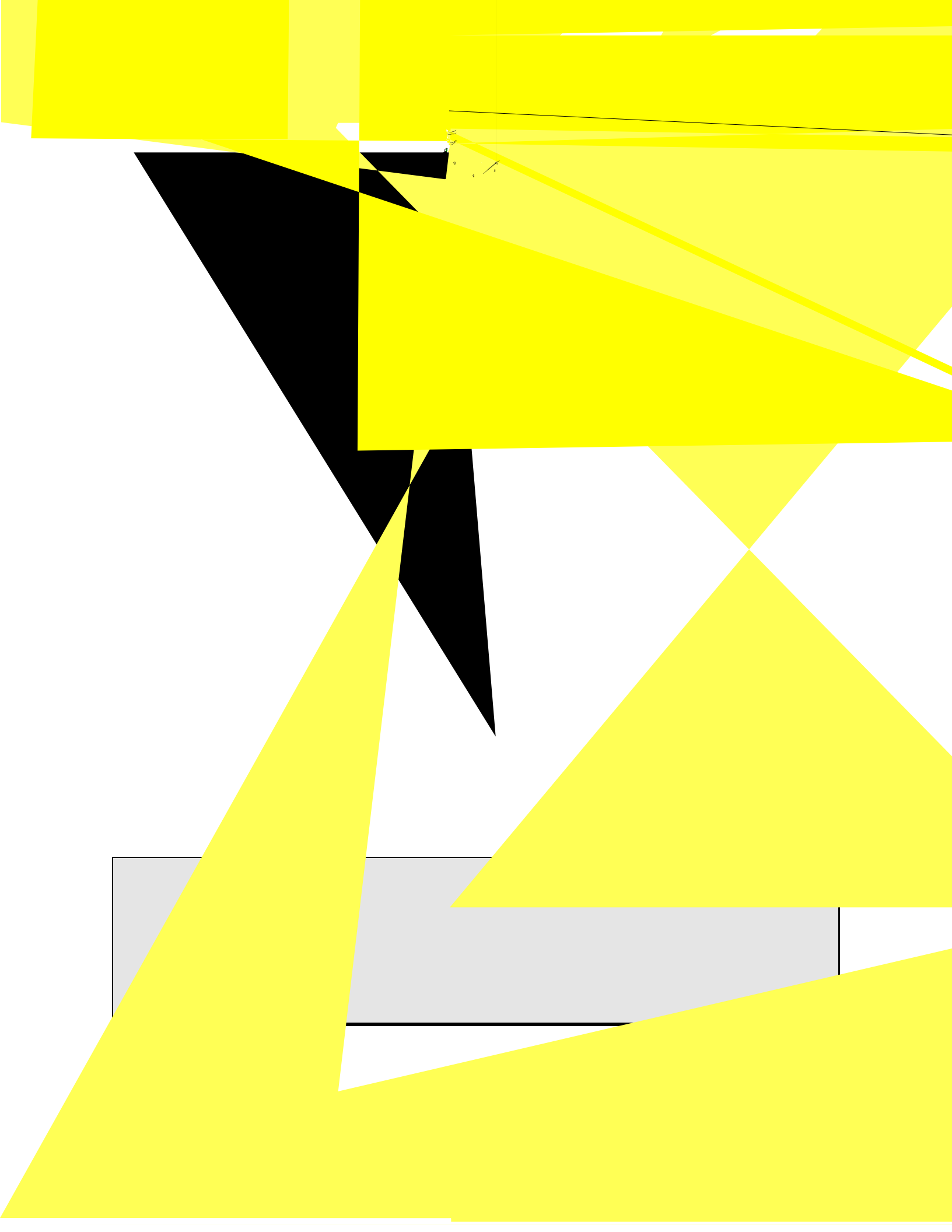
- 1300 Incident Response Actions - Responsibility and Authority (84-080)
- 1301 Response to Non-Emergency Incidents Involving Radioactive Material (96-022)
- 1302 Action Levels for Radiation Exposures and Contamination Associated with Material Events Involving Members of the Public (94-004)
- 1303 Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy (DOE) (95-009)
- 1330 Response to Transportation Accidents Involving Radioactive Materials (84-22)

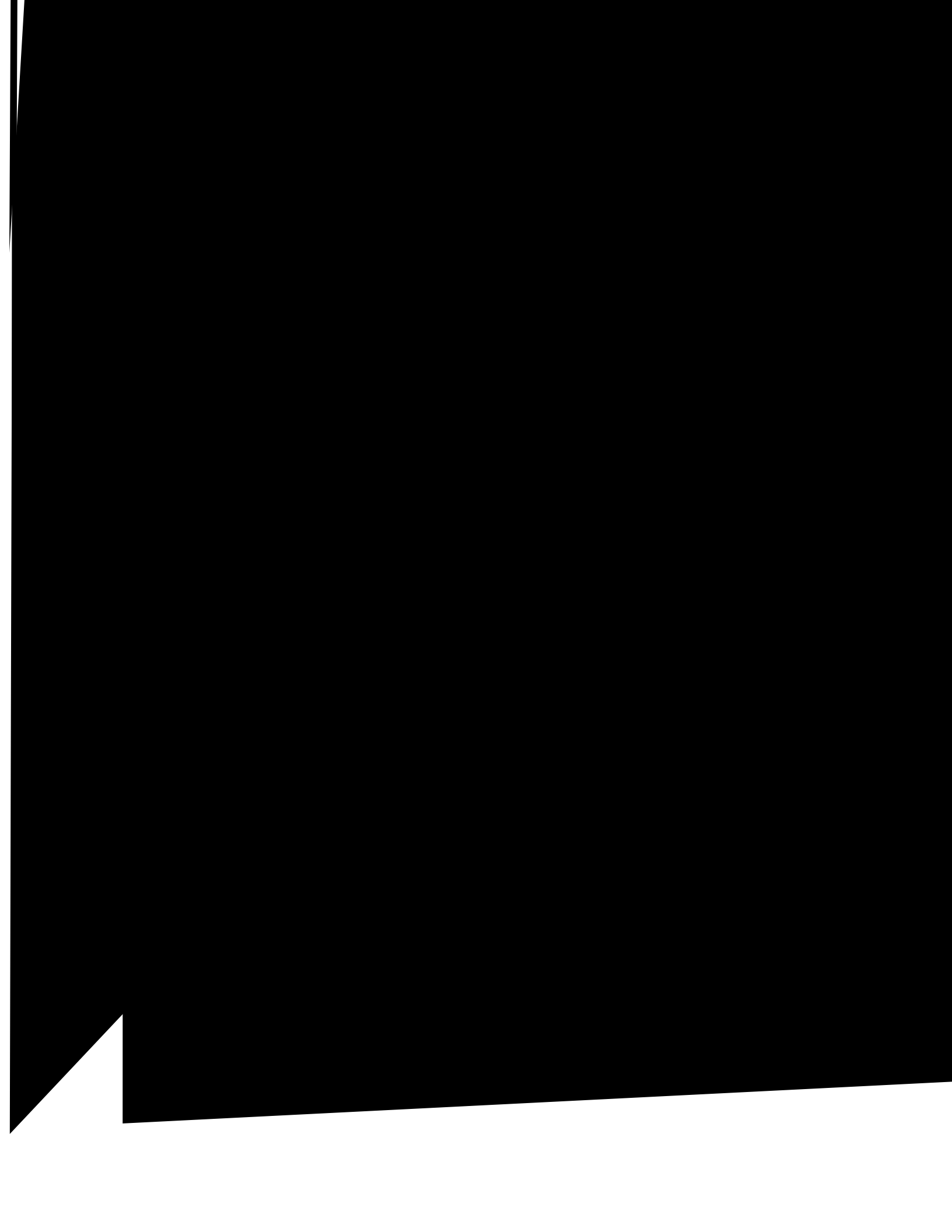
|

|

[illegible]







NMED accommodates the sharing of material event data submitted by Agreement States, non-Agreement States, and NRC licensees. NMED is maintained by the NRC's Office of Nuclear Material Safety and Safeguards (NMSS). The NMSS contractor, Idaho National ~~Engineering and Environmental~~ Laboratory (INEEL), is responsible for coding and quality control of information.

IV. ROLES AND RESPONSIBILITIES

- A. The Director, Office of State and Tribal Programs (STP), is responsible for the collection, coordination and, in cooperation with NMSS and the Office of Research (RES), the rey/05

and it was not previously reported to the NRC by the Agreement State under the 24-hour reporting requirement, the Events Project Manager should notify the HOO and the appropriate ~~regional~~ RSAO. If an event indicates the possibility of a generic

generic concerns are conducted by the Agreement States.
Information on any possible generic concerns



Abstract

The review and analysis of operational event information increases the effectiveness of the U.S. Nuclear Regulatory Commission (NRC) and Agreement State regulatory programs by identifying safety

information, including 30 day report information,

– *Events (NMED) Database Quarterly Report* is available in electronic form at the NMED Internet Website: <http://nmed.inl.gov>, <https://nmed.inl.gov>. A nuclear material newsletter, *NMSS Licensee Newsletter*, NUREG/BR-0117, is also published quarterly by NRC’s Office of Nuclear Material Safety and Safeguards (NMSS) that includes information on safety concerns identified during that quarter.

1.2 What helps governing regulatory authority?

- Under Section 274 of the AEA, Agreement States have assumed regulatory authority over byproduct source and certain quantities of special nuclear materials. The AEA directs Tm/to cooperate with the States in the formulation of standards to protect employees or ps tgeneral public against hazards of radiation and to assure that State and Commission programs will be coordinated and compatible. Article VI of the Agreement Between the State and the USTm/states that “the State and the Commission agree to keep each other informed of events, accidents, and licensee performa8.7 that may have generic implications or otherwise be of regulatory interest.”
- Under the AEA and the Energy Reorganization Act of 1974 (ERA), as amended, the Tm/evaluates material event reports for both NRC and Agreement State licensees, and AOs that have occurred in licensed facilities. In addition, the ERA requires Tm to provide to Congress on an annual basis, information on significant events that meet the AO criteria.
- Under the Government Performa8.7 Resu

contained in STP Procedure SA-200 (See Reference section).

-- The guidance contained in this handbook is to assist NRC and Agreement State staff

compatibility with the provisions of the Act. NRC conducts periodic evaluations of Agreement State programs under the



being evaluated with respect to inclusion of events involving NARM or discrete NORM. The States will be notified of any changes made to NMED. The database is maintained by NMSS through a contractor, Idaho National Engineering and Environmental Laboratory (INEEL).


1.5 Reporting Lost, Stolen and Abandoned Sources

Title 10 CFR 20.2201 mandates that each licensee report, by telephone, its discovery of any lost, stolen, or missing licensed material that exceeds specified quantities. Specifically, 10 CFR 20.2201(a)(1)(i) requires an immediate call if the licensed material



2. Reporting Material Events

In accordance with the provisions of compatible Agreement State regulations, Agreement

A rectangular gray box used to redact information.A rectangular gray box used to redact information.



~~MLB5@nrc.gov~~ or telephone: 301-415-5868. For contact via telephone, refer to the contact information on the homepage of the NMED website.

Access

d. *Internet*

An Internet (query only) version of NMED search of the nationally collected data is available on the website with several drop-down point-and-click menus available. Users may download the latest NMED national database information via Internet file transfer. Internet access to the NMED is currently

_____ Addresses through INL. If access is required, contact the INL NMED Project Manager by email message at: NMED@inl.gov Thomas W. Smith, INEEL by e-mail message at: _____

E-mail or fax, should be sent to the Director, STP or directly to the INL Project Manager at the address listed at the NMED homepage at <https://nmed.inl.gov>. Written TDport information should be comparable to the minimum basic information identified in Section 3



- c. Additionally, when providing follow-up NMED event information, provide clear reference to documents on file that the State used to generate the NMED event report, e.g., a licensee inspection report dated mm/dd/yr~~y~~., if applicable and appropriate.
- d. Any follow-up information that revises earlier information or provides additional information on a given event should be provided to ensure a complete historical NMED record.

EXHIBIT 2 - SAMPLE EVENT REPORT COVER PAGE

AGREEMENT STATE

EVENT REPORT ID NO. ____ - ____ - ____
(State\Yr.\No.)

DATE:

TO:

**Director
Office of State and Tribal Programs**

SUBJECT:

STATE:

Signature and Title: _____

Public Availability of Event Information: Any event information that is considered preliminary predecisional information by the State should be clearly identified

!

3. Closing and Completing Events

3.1 Events Closed in NMED





1

Reportable within 24 hours under 10 CFR Parts	

--	--

--



⁴ An “unintended radiation exposure” includes any occupational exposure, exposur

4. Series of events (where individual events are not of major importance), recurring incidents, and incidents with implications for similar facilities (generic incidents) that create a major safety concern.

⁶ The wrong radiopharmaceutical as used in the AO criterion for medical **events**

First paragraph - State the AO criteria for the event by citing the appropriate section of the AO criteria.

Date and Place - Provide the date the event occurred, the licensee's name, and the city and State address of the licensee.

Nature and Probable Consequences - Briefly explain the event ~~what happened~~

Table 4. Example 1: Radiopharmaceutical Exposure Write-up

State ID-Yr.-No
(~~XX-00-001~~)

Occupational Radiopharmacy Exposure at (Name of facility, City, State).

~~In accordance with the AO criteria an annual shallow-dose equivalent to the skin or extremities greater than 2500 mSv (250 rem) is considered an AO.~~ In accordance with the AO criteria I.A.1, "Human Exposure to Radiation from Licensed Material" any unintended radiation exposure to an adult (any individual 18 years of age or older resulting in an annual shallow-dose equivalent to the skin or extremities greater than 2,500 mSv (250 rem) is considered an AO.

Date and Place: [Date]; [Facility/Licensee]; [location] City, State.

Nature and Probable Consequences: A pharmacist trainee received an extremity exposure resulting in a shallow dose equivalent to the hand of 71402 mSv (742 rem) centiGray, (742 rads) to the hand; a deep dose equivalent of 70mSv centiSeivert

Table 5. Sample Medical AO Report
Example 2: Diagnostic Medical Event AO Write-up

State ID-YR-NO:
(XX-00-002)

_____ at (Name of Facility, City,

|

***Health effect to
patient***

The radiation oncologist did not anticipate any immediate adverse effect to the patient, and was not certain of the potential for any long-term effects as a result of the administration.

Consultant report

Appendix

Glossary

ADAMS	Agencywide Documents Access and Management System, NRC's official record electronic recordkeeping system, approved by the National Archives and Records Administration on April 1, 2000.
DPC	The Document Processing Center (DPC) is an internal NRC automated document search and retrieval system, indexed by a unique identification (Accession) No. for use by the staff of the NRC.
EN	The Event Notification (EN) system is an internal NRC automated event tracking system used by the NRC Operations Center to track information on incoming notifications of the occurrence of significant material events that have or may affect public health and safety. Significant material events are reported to the NRC Operations Center by NRC licensees, staff of the Agreement States, other Federal agencies, and the public. The EN's are published each work day through the Internet.
Gray	Gray (Gy) is the SI unit of absorbed dose. One Gray is equal to an absorbed dose of 1 joule/kilogram (100 rads).
Metric System	The metric system is now included in all Federal documents. All event reports should include the dual system of Units (SI) in the following order. First use the International System of Units (SI) with the English System unit equivalent following in parentheses. Spell out the first time it appears, continue with an

when radioactive materials are involved. In instances involving the suspected criminal misuse of nuclear material and byproduct material, your notification of the

Event Reporting Handbook

1. "Abstract"

Comment: Although we have been standardly changing occurrences of "misadministration" to "medical event" in all NRC documents, given that the audience is Agreement States, consider whether to continue use of the term "misadministration" to accompany the term "medical event" throughout the document. Given use of the term "medical event" is a category D compatibility item, the Agreement States are not required to adopt the word "medical event" and may choose to continue using the term "misadministration." (NMSS)

Response: The intent of this comment is valid. However, for Agency consistency, the term "medical event" will be used in SA-300. No changes will be made to the procedure based on this comment.

Response: We agree with the comments and revised Sections 2.2 and 2.4 describing the Event Identification Number, for consistency.

7. Section 4, *"NRC Publication and Distribution of Event Notifications"*

Comment: Modify section 4.1, "Event Notifications (ENs)," to indicate that the NRC will withhold Agreement State reports from public release for at least 48 hours. (Region I)

Response: Section 4.1 has been revised accordingly.

Comment: Section 4.2, *"Preliminary Notifications ."* Preliminary notifications are normally issued the same business day of the notification (or next business day if reported after release or on the weekend), not within two hours. (Region I)

Response: Section 4.2 has been revised accordingly. (Region I)

8. Section 5.1, *"NRC Review of Material Events for safety Significance and Generic Assessment"*

Comment: The last two paragraphs distinguish between significant and non-significant events and indicate that NRC staff may contact the State for significant events and the RSAO may contact the State for non-significant events. This contradicts Section I.V.F. of the procedure which indicates that the RSAO is the principal point of contact for the State. States have consistently given feedback to the NRC that they want one point of

STP-05-064, Opportunity to Comment on the Draft Revision to STP Procedure 300, "Reporting Materials Events (August 30, 2005), for medical licensees under AO Criteria proposes only to change the word "misadministration" to "event." (Utah)

- f. Move 39.77(b) to the significant reporting category and change the notification time to 24 hours. (Region I)
- g. Change the notification time for 39.77 (c) and (d) to 30 days. (Region I)
- h. Move the references for 40.60 and 70.50 to the corresponding 30.50

mentioned on page 5 of the "Event Reporting Handbook." We recommend that the 4 hour immediate notification be added to the table. (Region IV)

Response: We agree with the comments, and will revise the "*Event Reporting Schedule for Agreement States*," (*handy reference table*) to include immediate notifications (within 4-hours).

17. General Comments

Throughout document repp8c0radioisotope" and "isotope" with the word0radionuclide." (NMSS)

Response: We agree with this comment and will revise the procedure accordingly.

Although, not specifically requested during the comment period, information was added to the Event Reporting Handbook on NRC's Annual Agency Action Review Meeting (AARM). In accordance with SECY-02-216, "Proposed Process for Providing Information on Significant Nuclear Materials Issues and Adverse License Performance," Agreement State events will be considered, along with other materials licensees, for discussion during the AARM. The revised Management Directive and Handbook 8.14, "Agency Action Review Meeting," describes STP's participation in the AARM and its role as the